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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,032	06/29/2001	Christoph Seidel	HUBR-1067.3 DIV	2111
24972	7590	01/11/2005	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198			BROWN, TIMOTHY M	
			ART UNIT	PAPER NUMBER

1648

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/896,032

Applicant(s)

SEIDEL ET AL.

Examin r

Timothy M. Brown

Art Unit

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-- Th MAILING DATE of this communication appears on th cov r sheet with the correspondence address --
Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Final Office Action is responsive to the communication mailed October 22, 2004.

Claims 40-48 are under examination.

The status of the claims is as follows: the rejection of claims 40-48 for lacking enablement is maintained; the rejection of claims 43, 46 and 47 for lacking adequate written description is withdrawn; claims 40-48 are rejected under 35 U.S.C. 112, second paragraph based on new grounds necessitated by Applicants' amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite

for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claim 40 is indefinite in the recitation of "wherein said polypeptide has been modified at least one cysteine residue." This language is indefinite because it is unclear whether Applicants intended to claim (1) a polypeptide that has been modified at one or more cysteine residues (i.e. at at least one cysteine residue), or (2) a polypeptide that has been modified at one cysteine residue. This latter interpretation is based on the fact that omitting "least" would make the claim grammatical. For purposes of examination, it is assumed that Applicants intended the first interpretation.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most

nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably enable an immunologically reactive HCV NS3 polypeptide that has been modified at one or more cysteine residues.

“Undue experimentation” is defined by a number of factors including the breadth of the claims, the level of predictability in the art, the existence of working examples, and the quantity of experimentation that is needed to make and use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

As noted by Applicants, reducing the cysteine residues of NS3 using DTT improved the ability of serum antibodies to recognize NS3 antigen (Remarks p. 4). Applicants point to the results of Example 5 which demonstrate that reducing NS3 cysteine residues dramatically improves the ability of the NS3 antigen to bind serum antibodies. This demonstrates that NS3’s antigenicity is strongly determined by its cysteine residues. Therefore, any modification to the cysteine residues of NS3 has the potential to destroy the immunological activity of the NS3 polypeptide.

Turning to the Wands analysis, the breadth of the claims provides that Applicants’ immunogenic NS3 polypeptide may be modified at each cysteine residue using any modification known in the art. Thus, Applicants’ NS3 polypeptide may be modified by deleting each cysteine residue. As noted above, Experiment 5 suggests this would likely destroy the immunological activity of the NS3 polypeptide. It is also noteworthy that Applicants’ specification provides little direction on how one skilled in the art could use such an NS3 polypeptide to bind and detect HCV serum specific antibody - the only functional NS3 modification the specification teaches is the use of DTT. This does not teach one skilled in the art how to make and use an NS3 antigen having the range of modifications claimed by Applicants. Therefore, Applicants’ specification fails to enable a method for detecting HCV specific seroconversion antibodies using the claimed NS3 polypeptide.

Response to Arguments

Applicants argue undue experimentation is not required to make an use an immunogenic NS3 polypeptide that has been modified at one or more cysteine residues. Applicants point to Experiment 5 noting that when the cysteine residues of an NS3 polypeptide were reduced using DTT, the polypeptide's ability to bind antibody actually improved. The Examiner notes however, that reduction by DTT is just one kind of modification. As noted above, the breadth of the claims provides that the cysteine residues may be "modified" using any procedure known in the art. The cysteine residues may be deleted, farnesylated, conjugated, cross-linked or labeled. Each of these modifications has the potential to disrupt the antigenicity of the NS3 polypeptide. Thus, the fact that the NS3 polypeptide retains its antigenicity when reduced with DTT does not establish that the specification enables each type of cysteine modification that is covered by the claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tmb

Handwritten signature of James C. Housel in black ink, with the date 1/10/05 written below it.

Timothy M. Brown
Examiner
Art Unit 1648

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600